UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

September 22, 1999

MEMORANDUM

SUBJECT: Acephate. List B Reregistration Case No. 0042/Chemical ID No. 103301. Response to Comments to the Draft Acephate HED Risk Assessment and Disciplinary Chapters for the Reregistration Eligibility Decision (RED) Document. DP Barcode D254649. No MRID No.

FROM: Felecia A. Fort, Chemist
Reregistration Branch I
Health Effects Division (7509C)

THRU: Christina Swartz, Chemist
Whang Phang, Ph.D., Branch Senior Scientist
Reregistration Branch I
Health Effects Division (7509C)

TO: Monica Alvarez
Special Review Branch
Special Review and Reregistration Division (7508W)

The comments presented below by Valent U.S.A. and the California Celery Research Advisory Board are in response to the Environmental Protection Agency's preliminary Acephate HED Risk Assessment and Disciplinary Chapters for the Reregistration Eligibility Decision (RED) Document as they pertain to the organophosphate compound acephate. Comments pertaining to Occupational and Residential Exposure (ORE) and Toxicology/Hazard Assessment will be addressed in the Revised ORE and Toxicology Reregistration Eligibility Decision (RED) documents, respectively. All comments pertaining to drinking water exposures will be addressed by the Environmental Fate and Effects Division (EFED). All comments pertaining to usage will be addressed by the Biological and Economic Analysis Division (BEAD). Consequently, the following comments which were received by HED will not be addressed herein.

- Valent comments pertaining to toxicology, ORE, and drinking water
- Scotts Company comments (addressed in the Revised ORE chapter).

- U.S. Mint Industry (Mint Usage Information) comments (will be addressed by BEAD)
- Cranberry Institute Comments (addressed in the Revised ORE chapter)
- California Celery Research Advisory Board comments relating to environmental fate and usage (will be addressed by EFED and BEAD, respectively).

Comments from Valent U.S.A. In the Preliminary Risk Assessment

HED acknowledges the receipt of residue studies on soybean processed commodities, cottonseed ginned products and hot peppers. The cottonseed and soybean studies will be reviewed and the data incorporated into the revised risk assessment. The hot pepper residue data submitted has been deemed supplementary and will be reviewed at a later date.

Registrant Comment

- The UV/VIS study will be conducted in 1999. The requirement for corrosion characteristics should be waived because Orthene Technical is characterized as a dry powder (physical state). It is not corrosive as demonstrated by the lack of extreme pH of a 1% aqueous solution of the TGAI, pH 4.9. Packaging for the TGAI material for shipment and storage prior to formulating consists of an outer bag of polypropylene with a laminated five-ply polyethylene inner liner. Reaction between this inert polyethylene liner and the dry TGAI is unlikely.

HED Response

HED considers the registrants argument to be reasonable; however, additional information/data to support the registrants statement about packaging etc. should be submitted to justify waiving the requirements for corrosion characteristics.

Registrant Comment

- Valent elects not to support our 75% FI acephate formulation and will cancel this product registration.

HED Response

If the registrant cancels this product, no additional data will be required for the 75% FI acephate formulation

Registrant Comment

- **Page 5 & 6, Product Chemistry**. Valent submitted Product Chemistry Data to the Agency on September 17, 1998 and advised the Agency of our technical supplier. The Agency on January 21, 1999 advised Valent that our submitted product chemistry data have been reviewed and had been found to support our CSF and label.

HED Response

No additional data are required pertaining to the certification of suppliers of beginning materials and the manufacturing processes for the acephate MPs.

Registrant Comment

- The Agency stated that additional field trial data and a processing study are required before the established tolerances for residues of acephate per se in/on soybeans may be reassessed. A processing study has been submitted. No residue data are required for soybean forage and hay due to label restriction prohibiting grazing and cutting vines for forage or hay. Residue data for pre-plant (seed hopper box) application is not required since this application technique is not on the SLN label for soybeans. There is sufficient residue data on soybean seed for foliar application uses. In regards to the Agency's soybean aspirated grain fraction requirement, Valent believes this data requirement for aspirated grain fractions is not appropriate for acephate. Acephate is not used as a grain protectant. While our acephate (i.e. Orthene® PCO II formulation) may be used in food handling establishments, including grain storage facilities, it is only registered for crack and crevice use and would not contaminate stored soybeans. Finite acephate residues may be found in/on treated soybeans following treatment with Orthene. In the submitted processing study, the data demonstrates no concentration of residues in meal, oil and hulls, therefore, no food/feed additive tolerance for the process fractions are required. Residue levels in meal and hulls are equivalent indicating that the residues were primarily due to systemic uptake by the plant and not present as a surface residue on the soybean following foliar application of Orthene. The data demonstrate the soybean tolerance is sufficient for acephate residues in aspirated grain fractions (dust). Additionally, aspirated grain fractions should be viewed as a blended commodity. With Orthene's limited use on soybeans (<1% of total soybean acreage) acephate residues in blended grain elevator dust would be further reduced.

In the Agency's preliminary Residue Chemistry Chapter submitted to Valent on June 8, 1998, the Agency required data on cotton gin byproducts. Valent will conduct studies in 1999 to meet this requirement.

HED Response

The soybean processing study has been reviewed and the results will be incorporated into the Revised Human Health Assessment. HED agrees with the registrant that additional residue data are not required for soybeans *per se*.

HED agrees with the registrant's rationale for waiving the requirements for soybean aspirated grain fraction residue study. Recently submitted soybean residue data (MRID No. 447770-02) validate the registrant claim that there are no concentration of acephate residues in soybean meal or hulls. Further percent crop treated (%CT) data indicated that the %CT is <1%. A soybean aspirated grain fraction study is no longer required.

Registrant Comment

- Valent does not agree with the Agency's advisory to add a statement to our label which states that no methamidophos products should be applied after application of acephate since this may result in illegal residues. Valent has no knowledge of any illegal residues resulting from the use of acephate followed by methamidophos applications. Valent will conduct residue studies to support this position.

HED Response

HED has continuing concern that use of both acephate and methamidophos in the same season may result in illegal residues. Another option may be to amend labels to state that if both acephate and methamidophos are applied, the most restrictive PHI and seasonal application rate of the two labels should be used.

Registrant Comment

- **Acute and Chronic Dietary Exposure -- Food**. Acute and chronic dietary exposure and risk from both acephate and methamidophos (both as a metabolite from acephate

and from direct use) are acceptable. Using data and data-handling assumptions acceptable to the Agency, anticipated residues, proportion of crop treated, etc., chronic exposures do not exceed 2.8 percent for acephate and 5.8 percent for methamidophos of their respective chronic reference doses. Tier 3 acute dietary exposure and risk analyses, using field residue and monitoring data, yield acceptable margins of exposure for both compounds (100 for acephate and 300 for methamidophos).

Both acephate and methamidophos are analytes in the ARRI Market Basket Survey. More realistic residues in actual food will become available in the near future to further refine these analyses.

A detailed, but condensed version of the acute and chronic dietary exposure and risk analyses for acephate has been submitted. The full report of these analyses and all supporting information have been submitted to the Agency. The full report of the acute and chronic dietary exposure and risk analyses for methamidophos is to be submitted as part of the response to the draft methamidophos Reregistration Eligibility Decision document.

HED Response

HED will review the acute and chronic dietary exposure analyses submitted by the registrant and the results will be addressed in a separate memorandum.

Comments from the California Celery Research Advisory Board.

The response will only address comments pertaining to the dietary exposure.

Celery Board Comment

USEPA's conservative assumptions, used in calculating the potential dietary exposure, indicated overexposures with the current uses of acephate. The use of realistic data along with a more refined risk assessment would produce a more accurate estimate of exposure and in turn allow for better decisions to reduce overexposures that may be present. USEPA's acute risk assessment assumes that all the crops are treated at the maximum label rates and that 100% of the crop is treated. USEPA has tried to account for percent crop treated in the chronic dietary risk assessment; however, the agency did not provide any of the data used in the risk assessment on percent crop treated. Such information should be included for comment. Additionally, the use of tolerance level residues substantially contributes to the calculation of overexposure.

HED Response

HED agrees with the Celery Board's comments. The preliminary risk assessment was a Tier1 acute dietary assessment using worst case estimates, i.e. tolerance level residues and no percent crop treated data. A more refined probabilistic acute assessment which incorporates percent crop treated and anticipated residues will be conducted and included in the revised Human Health Assessment.